IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. ACINO PRODUCTS, LLC, a limited liability company and RAVI DESHPANDE, an individual, Defendants.	Civil Action No.: _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Acino Products, LLC, a limited liability company, and Ravi Deshpande, an individual (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. §§ 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Acino Products, LLC ("Acino" or "the firm") is a Delaware-incorporated limited liability company registered to do business in New Jersey. Acino operates at its principal place of business and drug manufacturing facility, which is located at 9B South Gold Drive, Hamilton, New Jersey (the "Facility"), within the jurisdiction of this Court.

5. Acino manufactures, processes, packs, labels, holds, and distributes a variety of prescription and over-the-counter drugs including, but not limited to, prescription hydrocortisone acetate 25 mg suppositories, the subject of this action. Acino packs and labels hydrocortisone acetate 25 mg suppositories under two separate brands, Rectacort-HC and GRx HiCort 25. Acino sells hydrocortisone acetate 25 mg suppositories labeled as Rectacort-HC to customers outside New Jersey, including customers in Kentucky and Pennsylvania. Acino contract manufactures, processes, packs, holds, and ships hydrocortisone acetate 25 mg suppositories labeled as GRx HiCort 25 for a pharmaceutical company located in New York.

6. Defendant Ravi Deshpande is Acino's president. He is responsible for, and has authority over, all operations at the firm. He has the authority and duty to prevent, detect, and correct objectionable conditions. Defendant Ravi Deshpande performs his duties at the Facility, within the jurisdiction of this Court.

7. Defendants manufacture drugs using components, including hydrocortisone acetate USP, that they receive in interstate commerce and introduce or deliver for introduction

finished drug products, hydrocortisone acetate 25 mg suppositories, into interstate commerce for shipment outside New Jersey.

DEFENDANTS' VIOLATIONS OF THE ACT

Unapproved New Drugs

8. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

9. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

10. The hydrocortisone acetate 25 mg suppositories Defendants introduce or deliver for introduction into interstate commerce, including the brands Rectacort-HC and GRxHiCort, are drugs within the meaning of the Act because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "intended to affect the structure or any function of the body of man," specifically, for use in treating inflamed hemorrhoids; post-irradiation (factitial) proctitis; as an adjunct in the treatment of chronic ulcerative colitis; cryptitis; and other inflammatory conditions of anorectum and pruritus ani.

11. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

12. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver, or cause to be introduced or delivered, into interstate commerce a new drug that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

13. The hydrocortisone acetate 25 mg suppositories Defendants introduce or deliver for introduction into interstate commerce, Rectacort-HC and GRxHiCort, are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1) because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

14. FDA does not have an NDA, ANDA, or IND on file for either Rectacort-HC or GRx HiCort. Accordingly, these prescription drug products are unapproved new drugs.

15. Defendants' introduction or delivery for introduction of hydrocortisone acetate 25 mg suppositories into interstate commerce therefore violates 21 U.S.C. § 331(d).

Misbranded Drugs

16. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

17. A drug is misbranded if its labeling fails to bear "adequate directions for use," and does not fall within a regulatory exemption from this requirement. 21 U.S.C. § 352(f)(1); 21 C.F.R. Part 201, Subpart D.

18. The hydrocortisone acetate 25 mg suppositories that Defendants introduce into interstate commerce are prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(B).

19. The prescription hydrocortisone acetate 25 mg suppositories Defendants introduce or deliver for introduction into interstate commerce are misbranded drugs because they do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.100 or 201.115. A new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its approved application. See 21 C.F.R. § 201.115. Thus, new drugs that lack an approved NDA, such as the prescription hydrocortisone acetate 25 mg suppositories, cannot satisfy this condition for exemption from the adequate directions for use requirement and therefore are misbranded until such time an NDA or ANDA for such drug is approved by FDA.

20. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drugs, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

21. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drugs, as defined by 21 U.S.C. § 321(g)(1), to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Interstate Commerce

22. During the most recent inspection of the Facility between January 12 and 25, 2015, FDA investigators documented Defendants' shipment of hydrocortisone acetate 25 mg suppositories, Rectacort-HC, from the Facility to recipients in Kentucky and Pennsylvania. FDA investigators also documented shipment of GRx HiCort 25 and Rectacort-HC from the Facility

to recipients outside New Jersey, including a customer in New York, during FDA's previous inspection between August 7 and 19, 2014. These shipments constitute the introduction or delivery for introduction of misbranded new drugs and unapproved drugs into interstate commerce under 21 U.S.C. §§ 331(a) and (d).

23. Defendants receive raw material from outside of New Jersey (including but not limited to the active pharmaceutical ingredient hydrocortisone acetate USP Defendants receive from Michigan), which they use to manufacture hydrocortisone acetate 25 mg suppositories. Therefore, the interstate commerce element under 21 U.S.C. § 331(k) is met.

HISTORY

24. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

25. FDA has conducted at least three inspections of the Facility, during February 6 – March 5, 2014; August 7 – 19, 2014; and January 12 – 25, 2015.

26. During the February/March 2014 inspection, FDA investigators documented Defendants' manufacturing and shipment in interstate commerce of hydrocortisone acetate 25 mg suppositories on behalf of Ascend Laboratories, LLC. At the conclusion of the inspection, Defendant Deshpande indicated that he was aware that hydrocortisone acetate 25 mg suppositories were being marketed by Ascend Laboratories, LLC as prescription drugs without an FDA-approved application.

27. In May 2014, the United States conducted a seizure of certain unapproved and misbranded drugs that were being distributed by Ascend Laboratories, including but not limited to hydrocortisone acetate 25 mg suppositories that Defendants had manufactured for Ascend Laboratories. The United States notified Defendants of the seizure by letter dated May 15, 2014.

The letter made clear that hydrocortisone acetate 25 mg suppositories were unapproved and misbranded drugs and were being seized in accordance with FDA's Compliance Policy Guide Section 440.100, Marketed New Drugs Without Approved NDAs or ANDAS, amended September 19, 2011 ("CPG Section 440.100"). 76 Fed. Reg. 58398 (Sept. 21, 2011). Under CPG Section 440.100, unapproved drug products introduced onto the market after September 19, 2011, would be subject to immediate enforcement action without prior notice and without respect to the enforcement priorities listed in the CPG. Id. at 58399.

28. At the conclusion of the August 2014 and January 2015 inspections, FDA investigators again discussed the unapproved status of hydrocortisone acetate 25 mg suppositories with Defendant Deshpande. Defendant Deshpande indicated that he was aware of CPG Section 440.100 and that he had been previously advised of the need to pursue FDA approval for the drug.

29. To date, Defendants have not filed an NDA, ANDA, or IND for unapproved drug products.

30. Based on their recent course of conduct, it is evident that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (d), and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any hydrocortisone acetate 25 mg suppositories, all formulations of those products, and the same or similar products designated by any other name, and any new drug unless and until an approved new drug application, an abbreviated new drug application, or an investigational new drug application Defendants filed pursuant to 21 U.S.C. §§ 355(a), (j), or (i) is in effect for such drugs.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, all hydrocortisone acetate 25 mg suppositories, including but not limited to those labeled as Rectacort-HC and GRx HiCort 25, and any product labeled similarly to such products and containing the same active ingredient(s) in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and

distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 5th day of June, 2015.

Respectfully submitted,

s/ Heide L. Herrmann
HEIDE L. HERRMANN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
202-532-4882
Heide.Herrmann@USDOJ.gov

PAUL J. FISHMAN
United States Attorney
District of New Jersey

By: s/ Bernard J. Cooney
BERNARD J. COONEY
Assistant United States Attorney

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation
Food and Drug Division

YEN HOANG
Associate Chief Counsel for Enforcement
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(240) 402-0484
Yen.Hoang@fda.hhs.gov